K070101

Sponsor: RITA Medical Systems, Inc

Contact Person: Kam Leung
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(510) 771-0440

FEB 14 2007

Summary Prepared: December 20, 2006

Trade Name: UniBlate Electrosurgical Device

Common Name: Electrosurgical cutting and coagulation device and accessories

Classification: Class II per 21 CFR 878.4400

Product Code: GEI

Predicate Devices: StarBurst XLi (K010060)
Cool-Tip RF System (K984552)

Intended Use:

The RITA Medical Systems UniBlate Electrosurgical Device is intended to coagulate tissue during percutaneous, laparoscopic, and intraoperative surgical procedures.

Description:

The UniBlate Electrosurgical Device is a monopolar radiofrequency (RF) device that consists of a variably insulated electrode. The instrument has an attached electrical cable and infusion tubing set which connects the device directly to the RITA Medical 1500X RF generator and the IntelliFlow peristaltic pump respectively. The electrical cable provides RF energy and temperature feedback to the generator and the pump infuses normal saline through the infusion tubing set. The UniBlate Electrosurgical Device is a single use device.

Technological Differences:

The RITA UniBlate, RITA StarBurst XLi (K010060) and Radionics Cool-Tip (K984552) are monopolar electrodes used to deliver RF energy during open, laparoscopic or percutaneous procedures to ablate and coagulate soft tissue. The UniBlate and StarBurst XLi devices are designed to provide a scaleable coagulation zone. The UniBlate electrode has a single active electrode that can be exposed

from 1 cm to 3 cm by retracting an insulating sheath. The StarBurst XLi consists of multiple electrodes which are deployed into the tissue from an insulated trocar. The Cool-Tip has a fixed length active electrode, but is available in different sizes. Both the UniBlate and StarBurst XLi allow for local fluid delivery as well as temperature monitoring. The UniBlate Electrosurgical Device is similar to the predicate RITA StarBurst XLi and Radionics Cool-Tip in principles of operation and construction and has the same intended use as the Cool-Tip.

Performance Data:

Performance testing was done to ensure that the UniBlate Device functions as intended and meets design specifications. Sufficient data was obtained to show that the device is substantially equivalent to the predicate device, and meets safety and effectiveness criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Underwriters Laboratories, Inc.
% Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
455 East Trimble Road
San Jose, California 95131-1230

FEB 14 2007

Re: K070101
Trade/Device Name: Uniblate Electrosurgical Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 29, 2007
Received: January 30, 2007

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 2
Indications for Use Statement

Indications for Use Statement

510(K) Number (if known) K070101

Device Name UniBlate Electrosurgical Device

Indications for Use:

The RITA Medical Systems UniBlate Electrosurgical Device is intended to coagulate tissue during percutaneous, laparoscopic, and intraoperative surgical procedures.

Division Sign-Off
Division of General, Restorative
and Neurological Devices
510(k) Number K070101

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(per 21 CFR 801.109)